



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
TEL 781.596.7700
FAX 781.596.7896

January 8, 2002

WARNING LETTER

NWE-10-02W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Boghos
President
Middle East Bakery, Inc.
1111 Riverside Drive
Methuen, MA 01844

Dear Mr. Boghos:

The Food & Drug Administration (FDA) has reviewed your label for *Joseph's Middle East 100% Stone Ground Whole Wheat Bread*, which was collected by FDA Investigator Christopher M. Elliott on June 29, 2001. Our review reveals that this label causes the above product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of federal Regulations (21 CFR), Part 101 – Food Labeling as follows:

The product is misbranded within the meaning of Section 403 (a)(1) of the Act in that its actual iron content is significantly less than the amount declared on the nutrition labeling. FDA's analysis of your product concluded it contained an actual iron content of 7.2% (percent daily value per serving) as compared to the 10% stated on the nutrition labeling.

The product is also misbranded within the meaning of Section 403(r)(1)(A) of the Act in that the label bears the nutrient claim "**No Fat Added**", which has not been authorized by FDA at this time.

In addition, the following labeling deficiency was also noted upon reviewing the product's nutrition information label:


- An asterisk as required under 21 CFR § 101.9(d)(9) does not precede the Percent Daily Values footnote.

The above violations concern certain new and current labeling requirements and are not meant to be an all-inclusive list of deficiencies. Labeling violations such as these may cause the product to be adulterated or misbranded within the meaning of the Act and, as such, subject to legal action without further notice, such as seizure and/or injunction. It is your responsibility to assure that all of your products are labeled in compliance with all applicable regulations enforced by FDA. Information regarding the food labeling regulations may be obtained through the Internet at <http://www.fda.gov>.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations along with a copy of the revised label. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time period within which the corrections will be completed.

Your reply should be directed to James A. DiNovo, Compliance Officer, U.S. Food & Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180. If you have any questions concerning the violations noted, please contact Mr. DiNovo by calling **781-596-7720**.

Sincerely,



Gail T. Costello, Director
New England District